PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, March 30, 2004, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Ms. Phyllis Cudmore; Mr. Manthala George, Jr., Ms. Maureen Pompeo (arrived at 10:25 a.m.); Ms. Janet Slemenda; Dr. Thomas Sterne; Mr. Gaylord Thayer, Jr.; and Dr. Martin Williams. Absent were: Commissioner/Chair Christine Ferguson, Mr. Albert Sherman and Donna Levin, General Counsel. Ms. Maryanne Fleckner, Associate Commissioner, acted as Chair until Deputy Commissioner Suzanne B. Thomson arrived. Attorney Susan Stein, Deputy General Counsel, acted as General Counsel for the entire meeting.

For the record, items not requiring a vote (i.e., Informational Items) were heard prior to the official meeting of the Council which occurred at the arrival of Deputy Commissioner Thomson.

The following members of the staff appeared before the Council during the informational or formal session of the Council to discuss and advise on matters pertaining to their particular interests: Mr.Ralph Timperi, Director, State Public Health Laboratory; Ms. Alexandria Kearns, Program Coordinator, Alcohol and Drug Counselor, Licensing Unit, Bureau of Substance Abuse Services; .Ms.Joyce James, Director, Determination of Need Program; Mr. Robert Walker, Director, Radiation Control Program; Dr. Susan Gershman, Director, Massachusetts Cancer Registry; Dr. Grant Carroll, Director, Drug Control Program; and Deputy General Counsels, Carol Balulescu and Howard Saxner, Office of the General Counsel.

INFORMATIONAL BRIEFINGS:

STAFF PRESENTATION: "MDPH Releases 2004 West Nile Virus/Eastern Equine Encephalitis Surveillance and Response Plan", by Ralph Timperi, Director, State Public Health Laboratory

The Department has a mosquito disease surveillance program that has been in existence for a long time, and is very well established and provides warning to the Commonwealth to hopefully reduce the risk of human disease. The two diseases that occur in Massachusetts are West Nile Virus and Eastern Equine Encephalitis. West Nile Virus is a very new disease, introduced in the United States in 1999, had occurred elsewhere in the world, but never in the Western Hemisphere, and the first human case in Massachusetts occurred in 2001. West Nile Virus belongs to a group of viruses known as flaviviruses. Some of the other ones in that family that you might have heard about are Yellow Fever and Dengue. St. Louis Encephalitis occurs in the United States, but not in Massachusetts. Eastern Encephalitis and the flaviviruses can be transmitted by mosquito or ticks. Different viruses are transmitted by ticks and some by mosquito. West Nile Virus is transmitted by mosquito. Eastern Encephalitis belongs to the family alphavirus and Venezuelan Equine Encephalitis. Western Equine Encephalitis, not surprisingly

occurs in the Western part of the Unites States and Venezuelan on the East Coast of South America. These viruses got the name Equine in there because the diseases were first recognized in horses, which obviously can be very noticeable when they get neurological disease. Eastern Equine Encephalitis, as well as the other members of this family cause very severe illness. Almost every case is a severe case and the mortality is much higher than West Nile Virus."

Mr. Timperi, continued, "…West Nile Virus doesn't cause mortality anywhere else in the world except in the United States. West Nile Virus causes very high mortality among crows and also blue Jays. The infections occur every year. Just as with any infectious disease, it cycles through population. You get outbreaks and then it wanes because the birds become immune. In order for the disease to be in an outbreak situation, you have to have lots of viremic birds. In the United States, it spread very rapidly because the bird populations in the United States are all susceptible to this virus. In the years when there are lots of infected birds flying around these occasional events occur where a mosquito first feeds on an infected bird and then lays its eggs. The female mosquito then feeds a second time, before it lays its eggs, on a human. Now, this chance event fortunately is rare. Mosquitoes don't live very long. In order to transmit, it has to have been a bird that was viremic at the time, with virus circulating, so humans and horses and other vertebrates, mammals are accidental dead end hosts of this disease and it is a cyclical disease."

Mr. Timperi continued, "In this country, West Nile Virus occurred first in the Queens area of New York in 1999. By 2003, it spread across nearly the entire country. The major outbreak last year was in Colorado. They had over two thousand cases, none recorded in Washington or Oregon and only three in California. Everyone will be watching this year to see if there is a much higher incidence of the disease on the West Coast this year. Eastern Encephalitis has only been known to occur in nineteen states in the United States and it is not going to move anywhere. This is pretty much where it settled in because of the mosquito species that carry this virus and other ecological conditions. These are the only states that are really at risk of this particular disease. First, West Nile Virus affects mostly the elderly and the risk of serious disease increases with age. With Eastern Equine Encephalitis it is the opposite. The highest risk is for younger individuals, between the ages of zero and nine and the mortality is much higher with this disease. West Nile Virus being a milder disease carries another risk that Eastern Encephalitis does not, and that is, many people become infected and only have mild disease. So what happens is, because they are not aware that they are ill, well-appearing people can donate blood and what happened in 2002 is 23 people were found to have gotten a West Nile infection from a unit of blood that was carrying the virus."

Mr. Timperi noted further, "What happened in 2003 was an investigational new test was developed and implemented so that, by July 14 of last year, all blood donations were screened by this new nucleic acid test, a molecular test for the virus, and pools of blood donations are tested at one time, and in 2003, 601 out of two and a half million donations were found to be viremic and removed from the blood supply, including one from Massachusetts. Now, there still remain some problems – the current testing isn't as

sensitive as we would like. So, there is a follow-up to look at blood donations that were not detected by screening from last year. Currently, all blood banks screen and exclude from donations all people with fever and headache and they also test every donation but in a pool format. What is probably going to be coming this year is, hopefully, either a more sensitive test will be developed to be certain units don't slip through, or they are going to have to drop down and screen individual blood donations."

Mr. Timperi said, "…Citizens call in dead bird reports in Massachusetts, and that is an early warning indicator. It is sensitive but not very specific. So, any place we had a human case, we had dead birds, but many, many places we had dead birds that were infected and we didn't have human cases….A more specific indicator but not as sensitive is mosquito. We test mosquitoes throughout the state. We had human cases, 16 human cases last year in 15 towns. In seven of those towns, we found West Nile Virus in mosquitoes. It's a much closer association between finding infected mosquitoes and human diseases."

Mr. Timperi said further, "Contributing Risk Factors to West Nile Virus are groundwater levels because that relates to mosquito populations; heavy rainfall. Snow cover also protects the mosquito during the winter. If we start seeing Eastern Encephalitis or West Nile Virus early in the season (June to July) that is an indicator there may be increased risk…if there are a high number of bird deaths from these infections, increasing rate of infected mosquito, and high number of bridge vectors (mosquito that feed on both bird and humans). To get an infection the mosquito must first feed on an infected bird and then live long enough to feed on a human to spread the virus. Early appearances of disease in horses or humans is the most direct indication of the risk of an outbreak, and again, if that occurs early in the season, we are much more worried than if it happens on the tail end of the mosquito season. If we are seeing all of these things and virus activity is continuing, then we have a serious situation."

"For this year", Mr. Timperi noted, "We have established a 24/7 hotline so people can report dead birds. The Department will be testing crows and blue jays for West Nile Virus. Birds have a high mortality rate for West Nile but Eastern Equine Encephalitis will not kill birds. They get mild infections from it. So birds are only a warning for West Nile Virus. Mosquitoes will be tested throughout the state. We will work with veterinarians to watch for neurological disease in horses, and we work closely with hospitals and Boards of Health to look for any evidence of human meningitis and encephalitis…" It was noted that last year the State Laboratory tested 400 people who had meningitis or encephalitis, 16 of those Massachusetts residents had been infected with West Nile Virus. Mr. Timperi asked that people clean-up their back yards and that they do not leave any jars of water lying around – a place where mosquitoes can breed and hatch.

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON AMENDMENTS TO 105 CMR 168.000, LICENSURE OF ALCOHOL AND DRUG COUNSELORS:

Ms. Alexandria Kearns, Program Coordinator, Alcohol and Drug Counselor, Licensing Unit, Bureau of Substance Abuse Services, presented the Informational Briefing on Amendments to 105 CMR 168.000 – Licensure of Alcohol and Drug Counselors to the Council. She noted that in September 2002, pursuant to M.G.L. 111J, the Department of Public Health promulgated regulations to license Alcohol and Drug Counselors in the Commonwealth. Shortly, thereafter the Bureau of Substance Abuse Services, together with the Department's Budget Office and the Executive Office of Administration and Finance worked to establish a fee for the licensure of Alcohol and Drug Counselors and Assistants. Pursuant to the process prescribed by A&F for establishing agency fees, the Bureau proposed a fee of $100.00 based on its study and research of similar licensure fees in both the Commonwealth and other states. This proposed fee was approved by the Executive Office of Health and Human Services in December of 2003 and by A&F in February of 2004. The bureau plans to bring the proposed amendment to public hearing and then return to the Council for final action.
A brief discussion followed.

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 130.000, HOSPITAL LICENSURE, REGARDING PROCEDURES FOR CONSENT TO AUTOPSY:

Ms. Carol Balulescu, Deputy General Counsel, Office of the General Counsel, presented the proposed amendment to 105 CMR 130.000 to the Council. She noted in part, "The purpose of these amendments is to set forth minimum requirements for the consent to autopsy, including the disposition of organs removed during an autopsy. Autopsies are currently performed either by hospitals licensed by the Department or by the Medical Examiner's Office. Occasionally, a hospital will conduct an autopsy on behalf of the Medical Examiner's Office. The Department has no jurisdiction over autopsies performed pursuant to the Medical Examiner's authority; therefore, separate procedures are being drafted by the Medical Examiner's Office regarding notification to families of the Medical Examiner's protocols and procedures for autopsies."

Ms. Balulescu continued, "The current Hospital Licensure regulation does not address the procedures that hospitals must follow in obtaining consent to an autopsy, nor does it contain any guidance regarding consent to the disposition of organs following autopsy. The proposed amendments were developed using samples of existing autopsy consent forms used by various hospitals, the Sample Autopsy Consent and Authorization Form offered by the College of American Pathologists, and related language contained in 105 CMR 800.000: Required Requests for Anatomical Donations. A working draft was reviewed by representatives of the Massachusetts Hospital Association and a practicing pathologist, and the Department made revisions based on their comments."

The proposed amendments to 105 CMR 130.000 will require hospitals to do the following:

- Obtain consent in order to conduct an autopsy;

- Use a consent form that meets the minimum requirements set forth in the regulation;

- Return any organs removed during the autopsy (except for those organs for which prolonged fixation is required to complete the autopsy) with the body unless the person authorizing the autopsy directs otherwise. This will also apply to an autopsy performed at a hospital on behalf of the Medical Examiner's Office, once the Medical Examiner's Office has released the body and organs.

- Provide a copy of the consent form to the person who authorized the autopsy; and Establish written policies and procedures for obtaining and documenting consent to autopsy and disposition of organs.

- Establish the same order of priority for persons authorized to give consent as is specified in 105 CMR 800.030 (the regulation governing organ donation).

Discussion followed Council Member Dr. Sterne inquired about practices of the Medical Examiners Office. Atty. Balulescu, replied, "As noted in the memorandum given to you, the Department has been working with the Medical Examiner to develop parallel procedures. I think what the Medical Examiner's Office is going to do is provide, not a consent document, but a disclosure of exactly what procedures are followed during autopsies conducted under the auspices of the Medical Examiner's Office, and the procedures they will follow for the disposition of organs following those autopsies. I can't speak for them as to whether or not they intend to promulgate regulations. As I understand it, they are looking at basically a disclosure statement." Council Member Thayer, Jr. pointed out how vague the language is in regard to the rank of persons for consenting to an autopsy. Attorney Balulescu responded that staff has used the organ transplant donation regulations as a guide for the language proposed here but that they could certainly make it clearer than using the term "ranking". Dr. Sterne added, "If there is confusion, it could be clarified if Section A said, "persons authorized to give or decline". Again, Atty. Balulescu noted that they could make that change and said further, "We can certainly insert something in that section that makes it much more explicit, similar to in B where it says, if a member of the same class opposes, then the hospital should not perform an autopsy. We could certainly add a sentence that says if a higher class opposes, then no one in a lower class may authorize the autopsy."

The Department will release the proposed amendments for public hearing and comment and return to the Council with a final recommendation.

NO VOTE/INFORMATION ONLY

DETERMINATION OF NEED GUIDELINES:

INFORMATIONAL BRIEFING ON PROPOSED EXTENSION OF THE EXPIRATION DATE OF THE REVISED DETERMINATION OF NEED GUIDELINES FOR CHRONIC DISEASE AND ACUTE INPATIENT REHABILITATION SERVICES:

Ms. Joyce James, Director, Determination of Need Program, made an informational briefing on proposed extension of the expiration date of the revised DoN Guidelines for Chronic Disease and Acute Inpatient Rehabilitation Services. She noted:

"The purpose of this briefing is to inform the Public Health Council of Staff's plans to release for public comment the proposed extension of the expiration date of the attached revised Determination of Need Guidelines for Chronic Disease and Acute Inpatient Rehabilitation Services (the "Guidelines") from April 27, 2004 to April 27, 2005. The Guidelines allow for a one-time increase in beds, so during the proposed extension period only facilities that have not yet added beds under the Guidelines will be eligible to do so. During the period of extension, Department staff, in consultation with the Chronic Disease and Acute Inpatient Rehabilitation Services Technical Advisory Group (the "Technical Advisory Group"), will reexamine the Guidelines based on the most current utilization data available from the Division of Health Care Finance and Policy (DHCFP), and consider the impact of the new propective payment reimbursement system, the current nursing shortage, and other relevant factors on the utilization of and need for new services. The Technical Advisory Group recommends and Department Staff agrees that the revised guidelines should be extended for another year.

During the period of extension, Department Staff will also be working with the Technical Advisory Group on a problem which may or may not be addressed by the current Guidelines. A telephone survey by the Division of Health Care Quality during the recent influenza season showed few available medical/surgical beds in Metro Boston and only eight vacant medical/surgical beds in Worcester County. Several acute care hospitals have approached the Department with the suggestion that if there were more Long Term Care Hospitals (LTCHs) to which post-acute care patients in need of long term acute care services could be transferred, it would help to alleviate the medical/surgical bed shortages and the ensuing back-up of acute care services demand. LTCHs are primarily chronic disease hospitals certified and reimbursed by the Medicare Program of the Center for Medicare and Medicaid Services (CMS) to provide services to post-acute care patients with an average length of stay in excess of 25 days. Patients in LTCHs are generally medically complex and have conditions that include ventilator dependency, multiple medical system failures, complicated infectious conditions, wound care and post-surgical recuperation.

The Department will determine the need for additional LTCHs and address any unmet need in new or revised guidelines. In either case, Department Staff will return to Council

as soon as possible with new or revised guidelines for the Council's adoption.

Following the public comment period on the proposed extension of the expiration date of the existing Guidelines, Staff will return to the Council at its next meeting in April 27, 2004 for Council's approval."

NO VOTE/INFORMATION ONLY

NOTE: Associate Commissioner Maryann Fleckner called a five-minute break to await the arrival of the Deputy Commissioner.

OFFICIAL MEETING OF THE COUNCIL: TIME: 11:00 A.M.

Upon arrival of Deputy Commissioner Suzanne B. Thomson, the official meeting of the Council began at approximately 11:00 a.m. The same Council Members were present as for the informational items (see page one for attendance).

Acting Chair, Suzanne Thomson, announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A ½ and that official business of the Council would now begin.

ROUTINE ITEM:

RECORDS OF PREVIOUS PUBLIC HEALTH COUNCIL MEETING:

Records of the Public Health Council Meeting of January 27, 2004 had been presented to the Council for approval. After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the Records of January 27, 2004.

PERSONNEL ACTIONS:

REQUEST APPROVAL OF APPOINTMENTS AND REAPPOINTMENTS TO THE VARIOUS MEDICAL STAFFS OF TEWKSBURY HOSPITAL:

In letters dated March 22, 2004, Val Slayton, M.D., MPP, Interim Director of Medical Services, at Tewksbury Hospital, recommended approval of the appointments and reappointments to the various medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Interim Director of Medical Services of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointments and reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning March 1, 2004 to March 1, 2006:

APPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Alfred DeMaria, Jr., M.D.	Provisional/Active/Internal Medicine	41088
Thomas Horn, M.D.	Provisional/Active/Psychiatry	159012
Mikhail Mazo, M.D.	Provisional/Affiliate Psychiatry	208421
Janet Weisenberger, M.D.	Provisional Consultant/Psychiatry	75189
REAPPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
John Cusack, Ph.D	Allied Psychology	7105
Barry Foster, Psy.D	Allied Psychology	3779
Natalie Gershman, M.D.	Affiliate Psychiatry	152859
Habib Sioufi, M.D.	Affiliate/Consultant/Internal Medicine/Pathology	50579

REQUEST APPROVAL OF INITIAL APPOINTMENTS AND REAPPOINTMENTS TO THE MEDICAL AND ALLIED HEALTH PROFESSIONAL STAFFS OF LEMUEL SHATTUCK HOSPITAL:

In a letter dated March 8, 2004, Paul D. Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of initial appointments and reappointments to the medical and allied health professional staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital be approved as follows:

APPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Gerald Cioce, M.D.	Consultant/Internal Medicine	219884
Donald Tracy, M.D.	Consultant/Radiology	75774

REAPPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Mario Addabbo, M.D.	Active/Anesthesiology	209873
Katherine McGowan, M.D.	Consultant/IM;Infectious Disease	42007
Daniel Oates, M.D.	Consultant/Internal Medicine	215230
C.Samson Munn, M.D.	Active/Radiology	`44407
Paul Weigle, M.D.	Consultant/Psychiatry	209361
Bruce Kaster, M.D.	Active/Psychiatry	76271
Ruben Figueroa, DDS	Consultant/Dentistry	19876
Fred Heller, M.D.	Consultant/Orthopedic Surgery	37067
Thomas John, DPM	Consultant/Podiatry	1853

ALLIED HEALTH PROFESSIONAL REAPPOINTMENT:

Myung Soon Woo-Roderick, RNP – 181296

REQUEST APPROVAL OF THE REAPPOINTMENT OF ARTHUR SHER, M.D. TO THE CONSULTING MEDICAL STAFF OF WESTERN MASSACHUSETTS HOSPITAL:

In a letter dated March 12, 2004, Blake M. Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the reappointment of Arthur Sher, M.D. to the Consulting Medical Staff of Western Massachusetts Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the reappointment of Arthur Sher, M.D. to the Consulting Medical Staff of Western Massachusetts Hospital be approved as follows:

REAPPOINTMENT:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Arthur Sher, M.D.	Consultant/Dermatology	35317

REGULATIONS:

REQUEST FOR PROMULGATION OF NEW REGULATIONS 105 CMR 124.000: PROVISION OF THYROID BLOCKING AGENTS:

Robert Walker, Director, Radiation Control Program, presented the request for promulgation of Regulations 105 CMR 124.000 to the Council. He explained, "The term "thyroid blocking agents" refers to drugs for chemicals that can be ingested and that will prevent the absorption by the thyroid gland of radioactive isotopes of iodine that may be released to the environment during an accident at a nuclear power station. To date, the only thyroid blocking agent approved by the US Food and Drug Administration (FDA) is potassium iodide, known more commonly by its chemical symbol 'KI'. Massachusetts General Law Ch. 111, § 5K, was amended by the Legislature in December 2002 to require the Department of Public Health to provide thyroid blocking agents approved by the FDA to the cities and towns situated within the established ten-mile radius EPZs surrounding a nuclear power station. The statute further requires the Department to provide thyroid blocking agents approved by the FDA to the cities and towns situated on Cape Cod, Martha's Vineyard, Nantucket and Cape Ann which request such thyroid blocking agents. The statute authorizes the Department to assess the costs of this program to the owners of any nuclear power station in the Commonwealth, and to electric companies in the Commonwealth which own, in whole or in part, or purchase power from the Seabrook nuclear plant in New Hampshire. In order to comply with the statutory requirement to promulgate regulations governing the purchase and distribution of thyroid blocking agents, the Department is proposing new regulations entitled, 'Provision of Thyroid Blocking Agents'." It was noted that these regulations were presented to the Council for information purposes on January 27, 2004 and a public hearing had been held on March 11, 2004 in Boston.

A brief discussion followed, whereby, Dr. Sterne inquired about costs of the pills. He said, "Does the Department anticipate a battle over sharing and splitting of the cost based on the testimonies from the various parties? The reason for the question has not so much to do with the curiosity of the back fighting, but more to do with whether the intent of the plan is for the Department to purchase the medications first and worry about the repayment to the Department later, or whether the intent is to wait until the funding has been provided by agencies from whom the state hopes to receive funding and then distribute it. And if so, I would imagine in the latter plan there would be a lag time until the pills were effectively available." Mr. Walker replied, "To answer your questions in the order you asked them, yes, we do expect a problem with the funding because we sent letters to three electric distribution companies because we were told by the Department of Telecommunications and Energy that they did distribute power from Seabrook, but we were told by each of them that they don't do that anymore. So, that is going to leave only Pilgrim Station as the sole funder for this program, and they have said during their testimony that they would not be prepared to pay for any pills that were distributed on Cape Ann because of the geographical distance in their location and Cape Ann. There may be some outfall from that. The second part of your question had to do with whether

we need the funding first. I understand that the State Purchasing System requires that we get the funding before we place the orders. That may be an issue." Dr. Sterne said he would not vote for the regulations, "because I think the purchase ought to be made first and funding fought over later." It was noted that the cost would be approximately $350,000 dollars every five years (the shelf life of the pills being five years).

After consideration, upon motion made and duly seconded, it was voted : (Ms. Phyllis Cudmore; Mr. Manthala George, Jr., Ms. Maureen Pompeo; Ms. Janet Slemenda; Mr. Gaylord Thayer, Jr.; and Dr. Martin Williams in favor; Dr. Thomas Sterne opposed) to approve the **Request for Promulgation of New Regulations 105 CMR 124.000: Provision of Thyroid Blocking Agents**; that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit Number 14,782.**

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 301.000: CANCER REGISTRY:

Dr. Susan Gershman, Director, Massachusetts Cancer Registry, presented the request for promulgation of amendments to 105 CMR 301.000. Dr. Gershman noted in part, "…that under current regulation, as amended in 1995, any health care provider diagnosing a case of cancer in Massachusetts is required to report information on such malignant disease to the cancer registry….In 2002, Congress passed the Benign Brain Tumor Cancer Registries Amendment Act which requires states that participate in the CDC National Program of Cancer Registries to begin reporting of benign brain-related tumors to the state cancer registry. CDC is requiring state cancer registries to have reporting authority for benign brain-related tumors in 2004. The federal legislation specifically defines benign brain-related tumors which include tumors in the brain, central nervous system, and spinal cord. Since the original enabling legislation for the MCR was limited only to the collection of information related to malignant disease which does not include benign brain-related tumors, the Department believed it was necessary to amend this statute to expand the collection authority to include benign brain-related diseases in order to comply with this federal requirement and maintain federal funding. In addition to complying with this new federal requirement, the MCR believes that collection of information on benign brain-related tumors is important due to the fact that the sensitive location of these tumors can have life-threatening consequences. Further research is warranted on these potentially fatal tumors."

Dr. Gerhman continued, "In response to this new federal requirement, the Legislature included language in the latest supplemental budget which amends MGLc.111, §111B, to allow the MCR to also collect information related to benign brain-related tumors. Since reporting of benign brain-related tumors is not covered under existing MCR regulations, these proposed amendments would include reporting of benign brain-related tumors. The MCR anticipates that the additional reporting requirements for benign brain-related tumors will have a minimal impact on mandated reporters since there is already a process in place for malignant disease reporting to the Department and since many providers have already been providing data on benign brain-related tumors. The number of benign

brain-related tumors that are expected to be reported to the Department represents less than 1% of the total number of annual cancer cases reported to the Department. While many providers have been voluntarily providing benign brain-related tumor information, this voluntary collection of tumor data has been declining since the implementation of the federal privacy rules issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA)."

Dr. Gershman noted further that these amendments contain language changes to clarify what information is required to be reported and who is required to report; that these amendments were presented to the Public Health Council for information purposes on January 27, 2004 and that a public hearing was held on March 9, 2004, in Boston. Discussion followed whereby Council Member Thayer, Jr. made a motion to add a change to the proposed regulations -- that is to add the word "disease" after the word malignant where ever it occurs in the final regulations in order to make it clear to readers that all malignant cancers are reportable not just brain tumor disease to the Mass. Cancer Registry. Dr. Gershman agreed that it would be a good idea.

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve the **Request for Promulgation of Amendments to 105 CMR 301.000: Cancer Registry, including Mr. Thayer's modification to add the word "disease**" as noted above; and that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit Number 14,783**.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 700: IMPLEMENTATION OF M.G.L. c.94C (ADMINISTRATION OF NERVE AGENT ANTIDOTES AND EPINEPHRINE):

Dr. Grant Carrow, Director, Drug Control Program, presented the Request for Final Promulgation of Amendments to 105 CMR 700.000: Implementation of M.G.L.c.94C to the Council. Dr. Carrow said in part, "…We are here today to request the Public Health Council's approval for final promulgation of regulations to authorize administration of epinephrine and nerve agent antidotes by certain certified individuals as well as trained first responders and other non-medical staff utilizing autoinjectors in emergencies involving anaphylaxis or nerve agent release." The proposed regulations would permit:

1. Authorized public employees whose functions include emergency preparedness and response, including first responders, to administer prescribed epinephrine and approved nerve agent antidotes for force protection.

2. Authorized staff in municipal or state funded, operated or licensed programs to administer prescribed epinephrine to individuals served by such programs.

3. Certified EMS First Responders (EFRs) to administer Schedule VI medications to the public.

4. Authorized first responders to administer epinephrine to the public.

Dr. Carrow noted the rationale for the regulations. "Increasing concern about anaphylaxis, particularly among children and young adults, has placed emphasis on the need for improved emergency response mechanisms for programs operated by or overseen by the Commonwealth. Similarly, increasing focus on preparedness for municipal and public agency response to potential bioterrorism incidents has pointed up the need to have mechanisms in place to deliver nerve agent antidotes quickly to emergency workers for force protection."

Dr. Carrow noted, "The only substantive change that has been made to the proposed regulations, since the Council saw them last in December was to expand the ability of staff of municipalities to also administer epinephrine to people in their custody in programs that they run."

In conclusion, Dr. Carrow said, "Department Staff believe that the proposed regulations would reduce morbidity and mortality from exposure to antigens and organophosphate nerve agents. The regulations would permit the establishment of voluntary programs with the appropriate medical and drug controls. For these reasons, we request approval for final promulgation of the amended regulations."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve the **Request for Final Promulgation of Amendments to 105 CMR 700. Implementation of M.G.L.c.94C** (Administration of Nerve Agent Antidotes and Epinephrine); that a copy be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit Number 14,784.**

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The meeting adjourned at 11:20 a.m.

Suzanne Thomson
DeputyCommissioner
Acting Chair

LMH/lmh